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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/692,244

10/23/2003

Thomas E. Cross JR.

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MEDTRONIC, INC.
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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/692,244	Applicant(s) CROSS, THOMAS E.	
	Examiner George R. Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-55 is/are pending in the application.
4a) Of the above claim(s) 40-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 22-34, 37, 38 is/are rejected.
- 7) ☒ Claim(s) 35, 36 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 40-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 12/12/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20, 22-33, 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 22, and 24, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

In claim 1, "at least 1-1/2 inches (40 mm)" is vague since 1.5 inches does not equal 40 mm. Is the length at least 1.5 inches or at least 40 mm? Pick one.

In claim 9, the plurality of ring contacts connected to the electrical conductor is vague since it sounds as if there is only one conductor and each ring contact is connected to each conductor. It is suggested to first state there are a plurality of conductors and that each contact is connected to each conductor.

In claim 10, “insulting” is not spelled correctly and “insulting ring spacers” is inferentially included. It is suggested to first positively recite the spacers before they are used in the claim.

In claim 11, “by a laser weld” is vague since it sounds more like a method step or a product by process than an actual structural limitation.

In claim 12, “its” is vague since it is unclear what element "its" refers to. It is suggested to state the element instead of using "its".

In claims 13-15, "formed", "assembled together", "bonded together" , "after assembly and bonding" and "butt bonded" are vague since they are more like method steps or a product by process than structural limitations.

In claims 18-20 and 31-33, “at least 4 inches (100mm)”, etc. is vague.

In claims 22 and 24, “it” is vague.

In claim 23, "comprising" should be "comprises".

In claims 25 and 37, it is unclear if the “at least one rib” of the previous claim is being further limited to comprise a plurality of ribs or if the plurality of ribs is a separate element.

In claim 28, "the conductors" lacks antecedent basis and “butt bonded” sounds like a method step.

In claim 30, “at least 1-1/2 inches (40 mm)” is vague.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8-10, 20, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feler (6236892). Feler states that the electrodes are 4 mm long, have a separation of approximately 7 mm center to center (therefore approximately 2.5 mm apart) and has a separation of 9.5 mm, or 3-10 times the electrode separation (7.5-25 mm), between the first/offset group 30 and the other group 40 and therefore provides for the first group being offset from the end by approximately 40-55 mm. NOTE, the claims do not state that there are no electrodes located in the portion that is not offset. Feler also shows in the figures what appears to be a tubular lead body and ring contacts on the connector separated by the insulating lead body but does not expressly state so. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the implantable lead as taught by Feler, the use of a tubular lead body and ring contacts separated by insulating ring spaces on the connector since it was well known in the art that implantable leads use: a tubular lead body to provide the predictable results of a smooth, non-bruising lead body to be traversed through the body; and ring contacts on the connector separated by insulating ring spacers to provide the predictable results of mechanically and electrically connecting the lead to the pulse generator by allowing the lead or pulse generator to be slightly rotated but still electrically connect separately to the electrodes without a short occurring between the electrodes.

Claims 2-7, 11-17, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feler. Feler discloses the claimed invention except for the electrode apertures, the lead body butt bonded to the paddle, the ring contact laser welded to the conductor, the off-center connection of the conductor to the electrode, the paddle being two portions with offset butt-bondings along the

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width or with a groove for a stylet and bonding, or the lead body including a strut butt bonded to the paddle and having a stylet lumen and plurality of conductor channels. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead as taught by Feler, with the electrode apertures, the lead body butt bonded to the paddle, the ring contact laser welded to the conductor, the off-center connection of the conductor to the electrode, the paddle being two portions with offset butt-bondings along the width or with a groove for a stylet and bonding, or the lead body including a strut butt bonded to the paddle and having a stylet lumen and plurality of conductor channels since it was known in the art that implantable leads use: electrode apertures to provide the predictable results of allowing the electrodes to provide the stimulation field to a particular area without stimulating different areas and allow the device to be easily assembled with pre-fabricated pieces; the lead body butt bonded to the paddle to provide the predictable results of a quick assembly lead and that provides a secure conventional connection between the elements; the ring contact laser welded to the conductor to provide the predictable results of a secure, conventional electrical connection between two elements; the off-center connection of the conductor to the electrode to provide the predictable results of an improved electrical and mechanical connection of the conductor to the electrode and allow for easy explant of the lead without breakage of the conductors from the electrodes; the paddle being two portions with offset butt-bondings along the width or with a groove for a stylet and bonding to provide the predictable results of a lead that is easily and quickly assembled using conventional bonding techniques and that allow for the lead to be implanted with a stylet; and the lead body including a strut butt bonded to the paddle and having a stylet lumen and plurality of conductor channels to provide the predictable results of allowing

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the lead to be quickly assembled using conventional bonding techniques, allow the conductors to be uninsulated in each channel to provide a smaller lead body, and allow the lead to be implanted using a stylet.

Claims 18-20 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feler. Feler discloses the claimed invention except for the portion proximal the electrode array being at least 3 or 4 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead as taught by Feler, with the portion proximal the electrode array being at least 3 or 4 inches since it was known in the art that implantable leads use different lengths between stimulating portions and non-stimulating portions, such as with the portion proximal the electrode array being at least 3 or 4 inches, to provide the predictable results of allowing the electrode array to fit a particular patients anatomy and to provide different areas of stimulation to multiple areas of the body.

In the alternative, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the implantable lead as taught by Feler with the portion proximal the electrode array being at least 3 or 4 inches, because Applicant has not disclosed that with the portion proximal the electrode array being at least 3 or 4 inches provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with spacing of 40-55 mm as taught by Feler, because the electrode will provide the appropriate stimulation to a majority of patients.

Therefore, it would have been an obvious matter of design choice to modify Feler to obtain the invention as specified in the claim(s).

Claims 22 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feler. Feler discloses the claimed invention except for the anchor configured for the paddle to attach the paddle to tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead as taught by Feler, with the anchor configured for the paddle to attach the paddle to tissue since it was known in the art that implantable flat paddle leads use an anchor configured for the paddle to attach the paddle to tissue to provide the predictable results of securely anchoring the lead and electrodes to the tissue at the location where the electrodes are located to prevent the lead from moving and changing the stimulation field.

Allowable Subject Matter

Claims 35, 36, and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 23-27, 37, and 38 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Boiling, Putz, Wyler, Grill, and Firlik, are several examples of many showing the well known in the art elements listed above in the 103 rejections. In addition, Tyers, Latterell, or Fogarty are three examples of many showing the use of an anchor on the paddle to connect the implantable paddle to the tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762
GRE
3/3/08